UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,763	10/21/2005	John Thomas Brandt	X16303	3837

25885 7590 02/03/2009

ELI LILLY & COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
02/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/553,763	BRANDT ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The response filed on **11/7/08** has been entered.

2. Applicant's arguments filed ON 11/7/08 have been fully considered but they are not deemed to be persuasive.

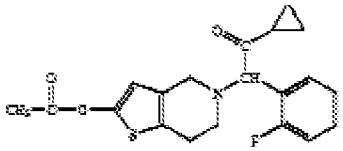
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-4 are pending in this office action. Claims 5-14 are cancelled.

5. Claims 1-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ogletree US 6,509,348 as evidence by Ekelund et al. (2001) for the reasons made of record in Paper No. 20080808 and as follows.

Applicant argues that Ogletree is mischaracterized because Ogletree specifically teaches the combination of an ADP receptor antagonist and a thromboxane A2 receptor antagonist optionally in combination with aspirin. Applicant argues that Ogletree does not teach the use of an ADP platelet aggregator without a thromboxane A2 receptor antagonist.

In response, the amendment “consisting essentially of” to the claims does not change the rejection, because “consisting essentially" is still open claim language, and because all that is required in the claims is to administer a compound and then perform a percutaneous coronary intervention procedure in “any order”.

Ogletree specifically disclosed CS-747 (i.e ) for the treatment of cardiovascular ischemic, myocardial infarction (known as acute coronary syndrome) after percutaneous coronary intervention (see col. 3, lines 53-65 and col. 4, lines 39-42). Ogletree also discloses aspirin maybe used with the claimed compound. (see col. 31, lines 31-37 as required by instant claims 2 and 3).

6. Claims 1-4 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Asai et al., (EP1350511, translated version of WO 02/051412) in view of Mehta et al. (2001) for the reasons made of record in Paper No. 20080808 and as follows.

Applicant argues that the instant claims are unobvious due to the unexpectedly superior results obtained with the compound of formula I in conjunction with PCI in the TIMI TRITON-38 study. That the TIMI TRITON-38 study compared prasugrel versus clopidogrel (the compound in the Mehta and Smith references) in a study of 13,608 patients with acute coronary syndromes undergoing PCI. Wiviott et al. (In, Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes, N. England J. Med. 357(20) 2001 (2007)) concluded that "[I]n patients with acute coronary syndromes with

scheduled percutaneous coronary intervention, prasugrel therapy was associated with significantly reduced rates of ischemic events, including stent thrombosis, but with an increased risk of major bleeding, including fatal bleeding" (emphasis added). Applicant also argues that the primary efficacy end point occurred in 12.1% of patients receiving clopidogrel and 9% of patient receiving prasugrel (hazard ratio for prasugrel vs. clopidogrel, 0.81; 95%). Applicant also asserts that Asai provides a list of diseases for which the compound of the present invention was deemed useful.

In response, Applicant relies heavily on Wiviott et al stating that prasugrel vs. clopidogrel were compared in patients with acute coronary syndrome and concluded that the therapy was associated with significantly reduced rates of ischemic. Thus the argument of showing unexpected results is not unexpected as it is known that the combination reduces ischemic effect. As to the argument that it causes increased risk of major bleeding, this has no effect on the claims because risk factors are not recited in the claim. It is further well known in the art of treating a condition that side effects play a role in the treatment. Nonetheless, the claims do not recite that any combination must not have any side effects upon treatment.

Note Applicant has not provided the Wiviott et al., in Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes, N. England J. Med. 357(20) 2001 (2007) for the Examiner's consideration. Again, the instant claims recite a method of treating acute coronary syndrome by administering compounds of formula I and performing a percurtaneous coronary intervention (for claim 1) and/or in combination with aspirin (instant claim 3).

Careful consideration has been given to the remarks and the unexpected result but they are not persuasive for the above reasons. The rejection is maintained as in the last office action dated 12/14/07.

7. No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. V. G./
Examiner, Art Unit 1618
1/26/08

/Robert C. Hayes/
Primary Examiner, Art Unit 1649